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AMENDMENT 1
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Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices

AMENDMENT 1: Revision of Annex E, Single batch release

Stérilisation des produits de santé — Oxyde d'éthylène — Exigences de développement, de validation et de contrôle de routine d'un processus de stérilisation pour des dispositifs médicaux

AMENDEMENT 1: Révision de l'Annexe E, Libération d'un lot unique

Reference number
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Foreword

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This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

As a result of this amendment, the following changes have been made to Annex E:

— clarification on the application of the method i.e. for research and development of new product or for clinical trial product;

— clarification that data resulting from a single batch release study can be used to support a full validation study;

— clarification that temperature and relative humidity sensors should be used to establish conditions in the sterilization load during both the half cycle and the full cycle comprising a single batch release.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Clause 2

Correct the publication year of ISO 11138-2 from 2009 to 2006.

Add the following and also a footnote “1) Under preparation”.

ISO 11138-7: —[1)] Sterilization of health care products — Biological indicators — Part 7: Guidance for the selection, use and interpretation of results

Annex E

Replace Annex E with the following: